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K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
SMITH, PRESTON	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/564,805
Filing Date: May 17, 2006
Appellant(s): SECRETIN, MARIE-CRISTINE

M. Secretin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/21/2011 appealing from the Office action mailed 01/19/2011

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1 and 5-21 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(**8) Evidence Relied Upon**

Susan E. Carlson, US-Patent 6,306,908

Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578

Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata

Bifidobacterial NPL

Zdenek Kratky, US-Patent 6,777,391

Threonine NPL

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,5-6, 9, 14-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 as evidenced by Bifidobacterial NPL and DHA NPL.

Regarding claim 1,6,9,14,16, Carlson teaches a "formula" (infant, see column 3, line 47 and line 65) comprising protein, carbohydrates, and lipids (column 11, line 27). As seen in table IV, column 13, lines 5-31, arachidonic acid and docosahexaenoic acid may be present in 0.41 weight % (22 mg) and 0.14 weight % (7 mg) respectively (column 13, lines 36-41). Additionally, the amounts of arachidonic acid may range from 1.0-60 mg (column 3, lines 66-67) and the amounts of docosahexaenoic acid may range from 0.25-35 mg (column 4, line 1) in the formula.

Carlson fails to explicitly teach docosahexaenoic acid being present in an amount of 0.2 – 0.5 % of the fatty acids and the formula further comprising a probiotic.

Although Carlson fails to explicitly teach arachidonic acid and docosahexaenoic acid both being present in the formula wherein the docosahexaenoic acid amount is 0.2-0.5%, Carlson does teach that the amount of docosahexaenoic acid may range from 0.25 – 35 mg as discussed previously (the 0.14% discussed previously pertains to 7 mg being present. Carlson teaches up to amounts over 4 times greater than 7 mg in the boarder disclosure which would correspond to a much higher percentage than 0.14% if one of ordinary skill chose to look to the boarder disclosure and use the amounts discussed in the broader disclosure). In light of these teachings, one of ordinary skill in the art would have found it obvious to slightly increase the docosahexaenoic acid content to 7 mg (which results in 0.14%) to a slightly higher amount in order to boost the brain health boosting properties (produce known effects) of the formula (see docosahexaenoic acid NPL). Also, in light of the teachings discussed previously, the

claimed range would have been discoverable by routine experimentation by one of ordinary skill in the art seeking to boost the brain health enhancing properties of the "formula".

Halpin-Dohnalek teaches probiotics such as lactobacillus (***column 3, lines 44-48.*** the formula may additionally comprise bifidobacterium also as seen in ***column 3, lines 35-36***) for use in an infant formula (***column 4, lines 23-25***). It would be obvious to one of ordinary skill in the art at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocoltis, ***column 3, lines 45-50 of Carlson***) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's disease fighting properties (***column 1, lines 45-50*** of Halpin-Dohnalek). (Further, *Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model)*)

Additionally, referring to "strengthening natural immune defenses" and "reducing... morbidity" recited in claims 14 and 16 respectively, the formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Referring to claim 5, in the cited embodiment discussed in examiners address of claim 1, the arachidonic acid and the docosahexaenoic acid would be in an ratio of

1:0.34. If this ratio is scaled by a multiple of 1.2, the resulting equivalent ratio would be 1.2:0.4. Applicant's claimed range ranges from 0.8:1 - 1.2:1. Even though the range of the composite invention is not within the claimed range, slightly increasing the amount of docosahexaenoic acid in order to improve the healthiness of the composite invention (Docosahexaenoic acid is known to help with brain growth of infants (see DHA NPL).) would have been obvious and thus it is considered that discovering the claimed range would have been obvious in light of the composite invention.

Referring to claim 15, Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the composite invention would be nutritionally complete.

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata as evidenced by Bifidobacterial NPL.

Referring to claim 7, the references teach the invention of claim 6 and in particular, Halpin-Dohnalek teaches Bifidobacterium infantis(column 3, line 46) however Halpin-Dohnalek does not explicitly teach Bifidobacterium longum BB 536.

Ogata teaches that it is known in the art to add Bifidobacterium longum BB536 (1st paragraph of Ogata) to food product (see Yogurt section). It would have been obvious to one having ordinary skill in the art at the time of the invention to add Bifidobacterium longum BB536 to the formula of the composite invention discussed previously since this would enhance the health boosting properties of the formula (as can be seen in the second paragraph of the introduction, Bifidobacterium longum BB536 enhances immunity, bone density, and reduces cancer risk).

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1 as evidenced by Bifidobacterial NPL.

Referring to claim 8, the references teach the invention of claim 6 and in particular, Halpin-Dohnalek teaches lactobacillus reuteri (column 3, line 45) however Halpin-Dohnalek does not explicitly teach lactobacillus rhamnosus GG.

Van Hoey-De-Boer teaches that it is well known in the art to add lactobacilli such as lactobacillus rhamnosus GG (paragraph 18) to food products (paragraph 0003). It would have been obvious to one having ordinary skill in the art at the time of the invention to add lactobacillus rhamnosus GG to the composite invention discussed previously since this would enhance the health boosting properties of the invention (see

paragraphs 17-20 and 3-4. This probiotic has therapeutic effects on gasterointestinal diseases).

Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1 and Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata as evidenced by Bifidobacterial NPL.

Referring to claim 10, see examiner's address of claims 6, 8-9 for why this limitation would have been obvious.

Claims 11-13, 17-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Zdenek Kratky, US-Patent 6,777,391 as evidenced by Threonine NPL and Bifidobacterial NPL.

Referring to claim 11 and 17, the references teach the invention of claim 1 and in particular, Carlson teaches whey protein concentrate (column 11, line 15)

Carlson does not explicitly teach modified sweet whey proteins with no CGMP or reduced CGMP.

Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (***column 2, lines 36-37***). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the whey protein concentrate of Kratky with the modified sweet whey protein to reduce the threonine content of the protein (***column 2, lines 36-39***). It is widely known that threonine increases brain glycine which in turn affects neurotransmitter balance in the brain and thus has negative consequences for brain development in the postnatal stages of life (and further, threonine levels are sought to be reduced in infant products). **(see Threonine NPL)**

Referring again to **claim 11**, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to claim 12, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 60% falls does not fall within this range however it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the protein percentages, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980). Additionally, increasing the protein amount would boost the healthiness of the formula (proteins are well known to help with mammal growth).

Referring to claim 13, Kratky teaches proteins present at less than 2 g/100 kcal (***column 9, line 35***).

Referring to claim 18, Krathy teaches that a preferred embodiment addresses the nutritional needs and provide for healthy growth of an infant (column 2, line 63-64). This is considered to provide complete nutritional needs of a baby or infant. Also,

Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the references would be nutritionally complete.

Referring to claim 19, the resulting composition of the references is considered to be capable of promoting healthy mental development in a preterm infant since it contains all of the components of the claimed composition.

The references do not explicitly teach using the composition to strengthen natural immune defenses of an infant or baby by feeding it to the preterm infant however, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May,* 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Further, while the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628. Additionally, the formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Referring to claim 20, Krathy teaches proteins present at 1.83 g/100 kcal which falls within the claimed range (***column 9, line 35***).

Referring to claim 21, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein

(column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

(10) Response to Argument

Applicant argues on page 13 that Carlson fails to teach or mention any percentages or the requirement of specific percentages of ARA and DHA in the total fatty acids in the lipid source as is required, in part by the present claims (see page 4). Carlson teaches a "formula" (infant, see column 3, line 47 and line 65) comprising protein, carbohydrates, and lipids (column 11, line 27). As seen in table IV (the table is based on the lipids), column 13, lines 5-31, arachidonic acid and docosahexaenoic acid

may be present in 0.41 weight % (22 mg) and 0.14 weight % (7 mg) respectively (column 13, lines 36-41). Also, Carlson mentiones that this is just one possible embodiment of ratios within the invention (column 13, lines 40-43). Additionally, the amounts of arachidonic acid may range from 1.0-60 mg (column 3, lines 66-67) and the amounts of docosahexaenoic acid may range from 0.25-35 mg (column 4, line 1) in the formula. Although Carlson fails to explicitly teach arachidonic acid and docosahexaenoic acid both being present in the formula wherein the docosahexaenoic acid amount is 0.2-0.5%, Carlson does teach that the amount of docosahexaenoic acid may range from 0.25 - 35 mg as discussed previously (the 0.14% discussed previously pertains to 7 mg being present. Carlson teaches up to amounts over 4 times greater than 7 mg which would correspond to a much higher percentage than 0.14% if one of ordinary skill chose to look to the boarder disclosure and use the amounts discussed in the broader disclosure) In light of these teachings, one of ordinary skill in the art would have found it obvious to slightly increase the docosahexaenoic acid content to 7 mg (which results in 0.14%) to a slightly higher amount in order to boost the brain health boosting properties (produce known effects) of the formula (see docosahexaenoic acid NPL). Also, in light of the teachings discussed previously, the claimed range would have been discoverable by routine experimentation by one of ordinary skill in the art seeking to boost the brain health enhancing properties of the "formula". (Additionally, adjusting other components of the formula would effect the weight percentages of the individual components.

Applicant argues that the formula has the unexpected result of improving the gut function and lowering infant intolerance to milk (page 14). Not only has applicant has not specifically claimed these alleged unexpected results but the probiotic such as lactobacillus of Halpin-Dohnalek improves gut function and lowers infant intolerance to milk. Both ARA/DHA and probiotics have well known functions and simply adding them together to obtain the effects in combination does not appear to be unexpected because these components are doing what is expected. This concept of adding components together to get multiple benefits from one formula or product is well known and clearly seen in substances such as multivitamins. For example, it is possible to buy vitamin A, C, etc alone or buy them in one formula. Taking these components individually would be expected to produce the same effects as taking them in one formula. Applicant has not discovered something unexpected by simply combining well known products with well known effects and then making a composite product having all the well known effects.

Applicant also argues that the other references references can not be combined to overcome the deficiencies of Carlson because each of the references is geared towards combating different problems (pages 15-16). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The references were used for the purposes stated in the office action.

Applicant argues that the references teach away from each other because they cure different things (page 16 and 17). Products such as mulitvitamins or serums that cure coughs, fever, etc combine multiple different products that cure or treat different problems into one product. Just because the different products cure different things doesn't mean that they shouldn't be combined into one product that can treat a range of problems.

Applicant argues that Kankaanpaa (reference provided by applicant) teaches that one of ordinary skill would have been deterred from combining probiotics and PUFA's (page 16). The Kankaanpa reference does not appear to establish that combining probiotics with PUFA's would be disadvantageous in the references cited by examiner. Just because Kankaanpa states that PUFA may influence the function of probiotics doens't mean that the combintation presented in the rejection woudlnt work.

Applicant argues that it's not proper to extrapolate weight percentages since they may change (page 22). See arguments regarding the obviousness of adjusting the DHA amount above.

Applicant also argues that Carlson fails to teach promoting the immune system (page 23). The formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Applicant also argues that Halpin-Donhnalek and Kraty fail to remedy the deficiencies of Carlson (see page 5, first paragraph). Halpin-Dohnalek teaches probiotics such as lactobacillus (column 3, lines 44-48. the formula may additionally

comprise bifidobacterium also as seen in column 3, lines 35-36) for use in an infant formula (column 4, lines 23-25). Carlson doesn't teach probiotics and thus Halpin-Dohnalek was considered to remedy this lacking feature. Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (column 2, lines 36-37). Carlson doesn't teach sweet whey proteins and thus Kratky was considered to remedy this lacking feature.

In response to applicant's arguments against the references individually (see page 21-25). The references were only used to teach concepts in the primary reference that were lacking), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (pages 23-25), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971)

In summary, applicant's invention is simply a "formula" with carbohydrates, proteins, ARA, DHA, and a probiotic. The supposed unexpected results of the formula with ARA,DHA, and a probiotic are not unexpected since we would expect these results to occur since the components individually have these effects so in combination it is expected to have the same effects.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Preston Smith/

Examiner 1782

Conferees:

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782

/SHRIVE BECK/
Supervisory Patent Examiner, Art Unit 1700